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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,955	01/15/2002	Michael S. Roberts	2370-84	5046

7590 03/09/2004

NIXON & VANDERHYE P.C.
8th Floor
1100 North Glebe Road
Arlington, VA 22201-4714

EXAMINER

BROWN, TIMOTHY M

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/044,955	ROBERTS ET AL	
	Examiner	Art Unit	
	Tim Brown	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-127 is/are pending in the application.
- 4a) Of the above claim(s) 1-77 and 81-127 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 78-80 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>see attached</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's election without traverse of group III in Paper No. 7 is acknowledged.
Accordingly, claims 78-80 have been examined.

Information Disclosure Statement

Various information disclosure statements filed by Applicants fail to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. Those documents that were missing were not considered as indicated by the redactions made on the various attached information disclosure statements.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 78-80 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 78 recites "said test virus" in line 15. There is insufficient antecedent basis for this limitation. Appropriate correction is required.

Claim 78 is also rejected under 35 U.S.C. 112, second paragraph for reciting "preferentially" in line 18. this term is a term of degree which renders the scope of the claim indefinite. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over McCormick (US 5,677,178) in view of Stiehm et al. ("UCLA conference. Interferon: immunobiology and clinical significance" Ann Intern Med. (January 1982) abstract only).

McCormick teaches a method for identifying a virus with anti-neoplastic activity in a mammal comprising:

using a virus to infect a) cells that are deficient in p53-mediated antiviral activity, and b) cells that are competent in p-53 mediated antiviral activity (abstract, lines 5-9; col. 3, lines 8-11; and col. 8, lines 33-46); and

determining whether said test virus kills said cells deficient in p53-mediated antiviral activity preferentially to said cells competent in p53-mediated antiviral activity (abstract, lines 9-13; col. 3, lines 13-16 and 49-54; and col. 8, lines 33-50).

McCormick does not expressly teach infecting cells that are deficient *in an interferon-mediated antiviral activity*. However, Stiehm et al. teach that interferons produce an antiviral state in uninfected cells by altering the nucleotide metabolism and cytoplasmic enzyme induction of non-infected cells (lines 1-3). At the time of Applicants' invention, it would have been obvious to one of ordinary skill in the art, to substitute McCormick's p53-mediated antiviral activity, with interferon-mediated antiviral activity as disclosed by Stiehm et al.

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One of ordinary skill would have been motivated to combine the teachings of McCormick and Stiehm et al. for at least two reasons. First, infecting cells having varying interferon-mediated activity would permit the method of McCormick to identify a different class of antineoplastic viruses. Second, McCormick's disclosure expressly suggests the asserted combination. McCormick states its method is "applicable to essentially *any virus type* wherein efficient replication requires binding and/or sequestration and/or *inactivation of a host cell protein* that is present in non-neoplastic cells but is substantially absent or non-functional in neoplastic cells" (col. 3, lines 26-29). The replication of virus in both McCormick and Stiehm et al. depends on the inactivation cellular proteins that inhibit viral infection. With McCormick, this protein is p53, while Stiehm et al. relies on interferon for inhibiting the replication of virus. Because McCormick provides that its method is applicable to any host cell protein that inhibits viral activity, one of ordinary skill in the art would have a reasonable expectation of success using interferon-deficient cells. Based on the foregoing, it would have been obvious to one of ordinary skill in the art to combine the teachings of McCormick and Stiehm et al..

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tim Brown whose telephone number is (571) 272-0773. The examiner can normally be reached on Monday - Friday, 8am - 5pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Tim Brown
Examiner
Art Unit 1648

tb


Shanon Foley
Patent Examiner
Art Unit 1648